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How much we can rely on the specific instability clinical tests to classify low back pain subjects into different instability categories

Submission date
23/12/2014

Recruitment status
No longer recruiting

Registration date
20/01/2015

Overall study status
Completed

Last Edited
09/02/2023

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Spinal physicians and physical therapist perform many tests to identify those who might suffer from specific low back pain due to inability of the back muscles and ligaments to control spinal movements during daily life activities. In this study we want to know how much we can rely on these test to reach the same diagnostic conclusion between different examiners. By performing these tests, will the examiners reach the same clinical decision making? If yes, the tests are reliable. If no, then we cannot rely on these test for clinical decision making.

Who can participate?
Adults suffering from lower back pain.

What does the study involve?
Examiners performing a series of tests.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Loma Linda University (USA)

When is the study starting and how long is it expected to run for?
February 2013 to June 2013

Who is funding the study?
Loma Linda University (USA)

Who is the main contact?
Faisal Alyazedi

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The Inter-Rater Reliability of Clinical Tests That Best Predict the Sub-classification of Lumbar Segmental Instability: Structural, Functional, and Combined Instability: a cross sectional study

Study objectives
The purpose of the study is to identify the inter-rater reliability of examiners performing clinical instability tests in order to identify different instability subgroups (structural, functional, and combined).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Loma Linda University's Institutional Review Board IRB# 5120285, 30/11/2012
The contact information of the Research Protection Programs is:
24887 Taylor Street, Suite 202, Loma Linda, CA 92350, USA
+1 (909) 558- 4531 (Voice). +1 (909) 558- 0131 (Fax)

Study design
Cross-Sectional Test-Retest Design

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
School

Study type(s)
Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied
Subjects with recurrent or chronic low-back pain (LBP)

Interventions
There was no intervention at all. Study conducted in the Physical Therapy Research Laboratory at Loma Linda University (USA).
Two examiners performed the six most validated clinical lumbar segmental instability tests-defined by highest +LR- on the subjects who had recurrent or chronic LBP, then sub-classify the subjects on three different lumbar segmental instability categories depending on the test results. We want to know if there is constancy in the decision making between the raters about the test results and the sub-classification. The tests are as follow:
• Passive lumbar extension test.
• Lumbar flexion ROM (> 53°) test.
• Lack of hypomobility with PA glide.
• Prone instability test (PIT)
• Aberrant motion present
• Average SLR (>91°)

Intervention Type
Other

Primary outcome measure
Kappa coefficient values for inter-rater reliability between the two examiners
The prevalence-adjusted, bias-adjusted Kappa (PABAK) values

Secondary outcome measures
The Baseline Measures (patients' characteristics) were collected at the beginning of the study, which included:
• the Numeric Pain Rating Scale (NPRS)
• the Modified Oswestry Low-back Pain Disability Questionnaire (OSW)
• and the Fear Avoidance Beliefs Questionnaire (FABQ)

Overall study start date
04/02/2013

Completion date
11/06/2013

Eligibility

Key inclusion criteria
1. Patients who have a new episode of LBP
2. Experienced a similar episode of LBP before, with the first episode of back pain occurring at least three months before the date of recruitment
3. Experienced persistent LBP for at least three months

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
40 subjects

Total final enrolment
40

Key exclusion criteria
1. Patients who have undergone previous spinal-fusion surgery
2. History of traumatic fracture of the spine that resulted in a permanent neurological deficit
3. Scoliosis greater than 20°
4. Pregnancy
5. Inability to actively flex and extend the spine adequately to permit an assessment of segmental motion due to pain or muscle spasm
6. Medical “red flags” such as caudaequina syndrome, tumor, and systemic inflammatory conditions

Date of first enrolment
04/02/2013

Date of final enrolment
11/06/2013

Locations

Countries of recruitment
United States of America

Study participating centre
Loma Linda University
School Of Allied Health Profession, Department Of Physical Therapy, Nichol Hall,

Loma Linda
United States of America
92350

Sponsor information

Organisation
Loma Linda University

Sponsor details
School Of Allied Health Profession
Department Of Physical Therapy
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California
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92350

Sponsor type
University/education

ROR
https://ror.org/04bj28v14

Funder(s)

Funder type
University/education

Funder Name
Loma Linda University

Results and Publications

Publication and dissemination plan
Submission to Journal of Manual and Manipulative therapy JMMT

Intention to publish date
31/12/2015

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/09/2015	09/02/2023	Yes	No